REMARKS

Claims 23, 33, 44 and 45 are currently amended. Claim 47 is new. It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 23, 25, 26, 28, 33, 34, 36, 38, 39, 43, and 44 under 35 U.S.C. 112 (Written Description)

Claims 23, 25, 26, 28, 33, 34, 36, 38, 39, 43, and 44 stand rejected under 35 U.S.C. 112, first paragraph as allegedly failing to comply with the written description requirement.

Applicants urge reconsideration in light of the amendments above.

Notwithstanding the amendments above, the rejection is respectfully traversed for the reasons of record. The written description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (*citing In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. *Id.* (*quoting Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985)); see also *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983). Quoting *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Company*, No. 2008-1248 (Fed. Cir. Mar. 22, 2010) (*en banc*).

The test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed. *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Company*, No. 2008-1248 (Fed. Cir. Mar. 22, 2010) (*en banc*).

Determining whether a patent complies with the written description requirement will necessarily vary depending on the context. *Capon v. Eshhar,* 418 F.3d 1349, 1357-58 (Fed. Cir. 2005). Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. *Id.* For generic claims, the Court of Appeals for the Federal Circuit have set forth a number of factors for evaluating the adequacy of the disclosure, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Id.* at 1359. *See Ariad*

Pharmaceuticals, Inc. v. Eli Lilly and Company, No. 2008-1248 (Fed. Cir. Mar. 22, 2010) (*en banc*).

The written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-67 (Fed. Cir. 2006). *See Ariad Pharmaceuticals, Inc. v. Eli Lilly and Company*, No. 2008-1248 (Fed. Cir. Mar. 22, 2010 (*en banc*).

Applicants respectfully maintain that the specification provides adequate written description support for the claimed invention.

Initially, Applicants maintain that the Examiner has erred by failing to take into account the sequence listings provided herein. Importantly, SEQ ID NO: 1 specifically shows the secretion stress inducible promoter including the nucleic acids 1-999 of SEQ ID NO.:1 or the ykdA promoter region. In addition, SEQ ID NO:1 includes an intact copy of the ykdA gene (nucleic acids 1000-2349 of SEQ ID NO.: 1). Moreover, SEQ ID NO: 1 shows the amino acid sequence for ykda protein also disclosed in SEQ ID NO:2. Clearly, SEQ ID NO:1 provides a secretion stress inducible promoter which is in its normal position linked to a gene encoding the amino acid sequence of SEQ ID NO:2.

Further, page 2, lines 24-29 of the specification states:

> In a third aspect, the invention relates to a method where the inducible promoter is comprised by or comprises the nucleic acids 1-999 of SEQ ID NO.:1.
> In a fourth aspect, the invention relates to a method where the inducible promoter is in its normal position the promoter linked to a gene encoding a polypeptide which has at least 70%, preferably 80%, or 90% or 95% or 98% identity to the amino acid sequence of SEQ ID NO.:2.

Given the maturity of the science, and that the specification provides: SEQ ID NOS: 1 and 2, and the language from the specification as a whole, one of skill in the art would understand that Applicants were in possession of the claimed secretion stress inducible promoters. Reconsideration is urged.

II. The Rejection of Claims 23, 25, 26, 28, 30, 31, 33, 34, 36, 38, 39, 41-46 under 35 U.S.C. 112 (Indefiniteness)

Reconsideration is urged in light of the amendments above.

Claim 44 is currently amended. Reconsideration is urged.

III. The Rejection of Claims 23, 25, 26, 28, 39, 43 and 44 under 35 U.S.C. 102(a)

Reconsideration is urged in light of the amendments above.

IV. The Rejection of Claims 23, 25, 26, 28, 39, 43 and 44 under 35 U.S.C. 102(b)

Claims 23, 25, 26, 28, 39, 43 and 44 stand rejected as anticipated by Jones et al. (Embo J. 16, 6394-6406, 1997) (hereinafter referred to simply as "Jones").

Reconsideration is urged in light of the amendments above.

V. The Rejection of Claims 30, 31, 33, 34, 36, 38, 41, 42, 45 and 46 under 35 U.S.C. 103(a)

Claims 30, 31, 33, 34, 36, 38, 41, 42, 45 and 46 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Lesley et al., Protein Eng. 15, pp. 153-160 (2002) ("Lesley") or Waldo, Curr. Opin. Chem. Biol., 7, pp. 33-38 (2003) ("Waldo") in view of Noone, J. Bacteriol., 183(2), pp. 654-663 (2001) ("Noone").

Reconsideration is urged in light of the amendments above.

VI. New Claims

New claim 45 is presented. No new matter is added. The required fees were charged to Novozymes North America, Inc.'s Deposit Account No. 50-1701 at the time of electronic filing. The USPTO is authorized to charge this Deposit Account should any additional fees be due.

VII. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

All required fees were charged to Novozymes North America, Inc.'s Deposit Account No. 50-1701 at the time of electronic filing. The USPTO is authorized to charge this Deposit Account should any additional fees be due.

Respectfully submitted,

Date: August 19, 2011

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